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10/595,042	06/01/2006	Tomislav Mihaljevic	BWY-005.01	1728

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FOLEY HOAG, LLP

PATENT GROUP, WORLD TRADE CENTER WEST

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EXAMINER

MARCETICH, ADAM M

ART UNIT

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3761

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/595,042

Applicant(s)

MIHALJEVIC ET AL.

Examiner

Adam Marcetich

Art Unit

3761

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-23 and 45-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-23 and 45-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,5-15,18-23,43,45,46 and 49-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens et al. (US Patent 5,702,368).

3. Regarding claim 1, Stevens discloses a method of cardioscopy and a cardioscopy apparatus comprising:

creating a primary heart bypass circuit for perfusing an organism (column 24, lines 17-21, column 25, lines 17-29, especially 25-29 and Fig. 16, withdrawing blood through inlets 218 and 219 and returning to patient through catheter 212 near external iliac artery. Stevens also discloses withdrawing blood from a venous system, passing it through CO2 removal and oxygenation, then returning it to the patient's arterial system, col. 5, lines 48-57, col 6, lines 19-30.);

creating a secondary circuit for perfusing the heart of the organism with a non-observation-impairing pumping medium (col. 24, lines 22-26 and Fig. 16, aperture 221 for infusion of saline. Stevens also discloses improving the visual acuity within the right atrium by saline infusion, col. 6, lines 30-36); and

observing the heart through the secondary circuit (column 25, lines 42-45 and Fig. 17, catheter 212 having instrumentation 237 including a cardioscope).

4. Regarding claims 3 and 12-15, Stevens discloses perfusing with saline, an optically clear, oxygenatable, translucent and non-turbid substance (column 24, lines 17-21).
5. Regarding claim 4, Stevens discloses treating a patient (column 5, lines 11-15). A living patient is inherently perfused with blood. Examiner interprets this claim broadly to include an organism that is inherently perfused with blood. In other words, during homeostasis an organism perfuses its tissues with blood.
6. Regarding claim 5, Stevens discloses a primary heart bypass circuit, receiving blood from a vena cava (col. 24, lines 11-16; Fig. 16, balloon 214 placed within superior vena cava 216; balloon 215 placed within inferior vena cava 217); and returning blood to the aorta (col. 24, lines 17-21, blood returned to patient and col. 25, lines 17-29, especially lines 25-29, continuous lumen 235 to return arterial blood from bypass. Also see col. 24, lines 55-56; Fig. 16, aortic balloon catheter 212 within aortic root 226).
7. Regarding claim 6, Stevens discloses a primary heart bypass circuit perfusing a coronary blood vessel (column 23, lines 7-23 and embodiment depicted in Fig. 2, coronary arteries 50 and 51).
8. Regarding claim 7, Stevens discloses a secondary circuit fluidically isolated from a primary heart bypass circuit (column 24, lines 17-26 and Fig. 16, blood drawn in through inlets 218 and 219, and saline infused through aperture 221).

9. Regarding claim 8, Stevens discloses a second circuit continuously perfusing the heart (column 24, lines 17-21 and column 25, lines 17-27). Examiner reads the language "continuously" broadly to include any time period.
10. Regarding claim 9, Stevens discloses a secondary circuit perfusing chambers of the heart (column 24, lines 22-26 and Fig. 16, perfusing right atrium 222 with saline; Examiner notes that saline infused into the right atrium naturally flows into the right ventricle. Therefore, both the right atrium and right ventricle are perfused by saline, interpreted as the claimed secondary circuit.).
11. Regarding claim 10, Stevens discloses a secondary heart bypass circuit perfusing a coronary blood vessel (column 25, lines 1-5, 17-25 and 34-39; Fig. 16, balloon 227 not occluding coronary arteries). The aortic root includes coronary blood vessels.
12. Regarding claim 11, Stevens discloses receiving pumping medium from the aorta and returning the pumping medium to a vena cava (column 25, lines 17-29; Fig. 21, venting lumen 233 to aorta and column 24, lines 22-26; Fig. 16, saline infused to aperture 221 within vena cava).
13. Regarding claims 18-23, Stevens discloses visualizing with an angioscope, visualizing the heart through a catheter, observing a heart chamber, observing a heart valve and performing an intracardiac procedure (column 25, lines 59-67 through column 26, lines 1-30 and Fig. 8, angioscope 67). Examiner reads the language "endoscope" broadly to include an angioscope.

14. Regarding claim 45, Stevens discloses a method further comprising allowing the heart to continue beating (column 4, lines 62-67 especially lines 65-66; methods and devices useful even where cardiac function is not arrested. Also see column 17, lines 11-23 especially lines 11-14, system further useful when cardiac function may not be arrested).
15. Regarding claim 46, Stevens discloses a secondary circuit perfusing only the organism' s right heart (col. 21, lines 48-65, retrograde cardioplegia balloon catheter 20 placed in right atrium 45).
16. Regarding claim 49, Stevens discloses antegrade flow through a secondary circuit (col. 33, lines 16-33, especially lines 16-21, embodiment of partitioning device 320 used for antegrade delivery of cardioplegic fluid to heart).
17. Regarding claims 51 and 52, Stevens discloses a secondary circuit comprising both a pump and oxygenator (col. 6, lines 37-53, especially line 46, pump oxygenator).
18. Regarding claim 50, Stevens discloses retrograde flow through a secondary circuit (col. 21, lines 48-65, retrograde catheter 20 for occluding coronary sinus 21).
19. Regarding claim 53, Stevens discloses a pumping medium comprising a cardioplegia agent (col. 24, lines 22-26, saline infused into right atrium 222). Examiner notes that saline is a cardioplegic agent when chilled. To restate, saline is interpreted as the claimed cardioplegic agent since it is used during cardioplegia.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US Patent 5,702,368).

23. Regarding claims 47 and 48, Stevens discloses a secondary circuit perfusing only the organism's right heart as discussed for claim 46 above. Stevens is silent regarding perfusing only the organism's left heart as claimed [claim 47] or creating an additional secondary circuit perfusing only the organism's right heart as claimed [claim 48]. However, Stevens discloses using the procedure to replace a mitral valve (col. 1, lines 31-41, especially lines 31-34 and col. 20, lines 35-46, especially lines 39-41, repair of mitral valve). The mitral valve is located in the left heart, between the left atrium and ventricle. Modifying the method of Stevens to perfuse only a left side of the heart allows

mitral valve replacement. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stevens as discussed by perfusing only an organism's left heart in order to replace a mitral valve. Regarding a limitation of the additional right heart perfusion, Stevens also discloses repairing a tricuspid valve (col. 17, lines 34-37, 58-59, tricuspid valve surgery), located in the right heart. Here also, perfusing only the right heart facilitates valve replacement.

24. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US Patent 5,702,368) in view of Loeb (US Patent 4,448,188).

25. Regarding claims 16 and 17, Stevens discloses the invention as substantially claimed. See above. However, Stevens lacks a perfluorocarbon. Loeb discloses a perfluorocarbon (column 2, lines 21-23 and column 5, lines 13-18). A perfluorocarbon is inherently a fluorocarbon. Loeb provides the advantage of visualizing an internal structure while maintaining adequate oxygenation to surrounding tissues (column 1, lines 62-68 through column 2, lines 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stevens as discussed with the perfluorocarbon as taught by Loeb in order to adequately oxygenate surrounding tissues.

26. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US Patent 5,702,368) in view of Cosgrove; Delos M. (US 6182664).

27. Regarding claim 54, Stevens discloses the invention substantially as claimed, see above. However, Stevens lacks a pumping pathway from the aorta to an organism's right atrium as claimed [claim 54]. Cosgrove discloses a method for minimally invasive cardiac surgery (col. 2, lines 13-29), also adapted for valve replacement surgery (col. 4, lines 57-67, especially lines 57-59). Cosgrove further discloses a circuit that includes:

receiving the pumping medium to the organism's right atrium (col. 6, lines 42-53, especially lines 45-46, first cannula 152 into inferior vena cava or right atrium 36); and
returning the pumping medium from the aorta (col. 6, lines 42-53, especially lines 50-53, third cannula 206 inserted into ascending aorta 30 for arterial return).

Examiner notes that this is a reverse of the claimed arrangement [claim 54]. Cosgrove further discloses a step where the flow through this circuit is reversed, providing a circuit pathway according to that claimed. Here, the circuit includes receiving the pumping medium from the aorta and returning the pumping medium to the organism's right atrium (col. 8, lines 20-30, suction applied to cardioplegia cannula 162). With this arrangement, Cosgrove provides the advantage of removing any air from the left ventricle which may have been introduced during valve surgery. To clarify, reversing the flow prevents any bubbles from into the lungs or vasculature. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stevens as discussed with the circuit pathway as taught by Cosgrove in order to remove air introduced during valve surgery.

Response to Arguments

28. Applicant's arguments, see p. 5-7 filed 29 October 2008 with respect to the rejection(s) of claim(s) 1 and 3-23 under 35 USC § 102 and 103 over Stevens and Loeb in view of have been fully considered but are not persuasive. Additionally, new claims 45-54 are rejected under 35 USC § 102 and 103 over Stevens and Cosgrove.

29. Applicant asserts that Stevens lacks the claimed secondary circuit, making an analogy to an electrical circuit. Examiner notes that the limitation of a "return to a first site" does not appear in the claims. In other words, the language "circuit" is not given a special definition. While Applicant provides an example of the claimed circuit at ¶ [22] of the immediate specification and Figs. 4-8, this is not interpreted as a special definition of "circuit." To restate, in this grounds of rejection, a fluid "circuit" is not strictly limited to pathways returning fluid to an original point. Fluid circuits are different from electrical circuits in that fluid is not required to return to an original point, since fluid pathways have the capability to source (through fluid stored in vessels or conduits) or sink (into expansible vessels, especially physiologic vessels or chambers) fluid volume without requiring return to an original point.

30. Applicant contends that the interpretation of Stevens is mistaken because the infused medium (saline) never circulates through a loop. Examiner notes that the language "circuit" is interpreted broadly as discussed above.

31. Applicant reasons that oxygenated blood returned to the patient in Stevens' primary bypass circuit cannot reach the coronary arteries, as required by claim 6, since his system isolates the heart and coronary blood vessels from the remainder of the

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arterial system, which is served by the primary bypass circuit. Examiner notes that fluid perfused to an aorta or left side of the heart will flow into coronary arteries, while perfusing blood into a right atrium will perfuse fluid to coronary veins.

32. Applicant asserts that the secondary circuit cited for claim 10 perfuses the heart rather than bypassing it, and that this infusion is unrelated to the right-atrial saline infusion that the Examiner cited as meeting the secondary circuit when rejecting claim 1. Examiner notes that in isolating circulation from the rest of the body, Stevens substantially bypasses the heart.

33. Applicant contends that Stevens lacks the limitations of claim 11, since the saline infused through aperture 221 stays "within the right heart" (col. 24, lines 22-26). Applicant notes that saline added to the vena cava does not come from the aorta, so it is not part of some secondary circuit with the left heart and specifically the aorta, and that catheter 226 (Fig. 16) may deliver a cardioplegic agent through lumen 233 (Fig. 21a), but such cardioplegic agent is not the same medium as the saline being infused into the vena cava. Examiner notes that the language "circuit" is interpreted broadly as discussed above, therefore these components are interpreted as the claimed receiving and returning steps.

34. Applicant asserts that Loeb fails to remedy shortcomings of Stevens. Examiner notes that Loeb is relied upon for the limitation of a perfluorocarbon liquid.

Conclusion

35. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

◆ Cosgrove; Delos M. US 5752526

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
15 January 2009